

## **REMARKS**

Claims 1-4, and 25-37 are pending in this application. Claims 5-24 have been withdrawn. Claims 1-4, 25-29, 31-37 have been rejected under 35 U.S.C. § 102(e). Claim 30 has been objected to but indicated as allowable. Dependent claim 30 has been rewritten in independent form by virtue of this amendment and dependent claim 35 has been amended to correct a typographical error.

### **Rejections under 35 U.S.C. § 102(e)**

#### *A. Claims 1-4 and 26-29, 31-37*

Claims 1-4 and 26-29, 31-37 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,043,080 to Lipshutz et al. (hereinafter “Lipshutz”). Applicants traverse this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently described in a single prior art reference. MPEP §2131. Applicants believe that Lipshutz does not anticipate the present invention because it does not set forth at least one of the claim elements of independent claims 1, 28 and 31. For example, independent claims 1, 28 and 31 recite that “the carrier is adapted to mate with the device to form a reaction chamber.” This claim limitation is not disclosed, taught or suggested in Lipshutz. The Office points to col. 4, lines 56-61 of Lipshutz which states:

Alternatively, the device may be provided with a hypodermic needle integrated within the device and connected to the sample collection chamber, for direct acquisition of the sample into the sample chamber. This can substantially reduce the opportunity for contamination of the sample.

Lipshutz, col. 4, lines 56-61. Herein, the hypodermic needle is integrated within the device and connected to the sample collection chamber for the direct acquisition of the sample into the sample chamber. The hypodermic needle in Lipshutz does not mate to form a chamber. The needle is connected to the chamber but does not mate to form a chamber as does the carrier of

the present invention as claimed. Instead, the needle in Lipshutz serves as a *channel or corridor* for the acquisition of sample into the sample *chamber*.

Furthermore, independent claims 1, 28 and 31 each state that the carrier is “adapted to introduce the sample to the reaction chamber upon mating the carrier to the device.” There is nothing in Lipshutz at col. 4, lines 56-61 to indicate that sample is introduced into the reaction chamber upon mating. In contrast, the hypodermic needle in Lipshutz is “*integrated* with the device and *connected* to the sample collection chamber”. (emphasis added)

Elsewhere, Lipshutz at col. 4, lines 48-56 states as follows:

Generally, this is carried out by introducing a sample for analysis, e.g., preamplified sample, tissue, blood, saliva, etc., directly into a sample collection chamber within the device. Typically, the prevention of cross-contamination of the sample may be accomplished by directly injecting the sample into the sample collection chamber through a sealable opening, e.g., an injection valve, or a septum. Generally, sealable valves are preferred to reduce any potential threat of leakage during or after sample injection.

Lipshutz, col. 4, lines 48-56. And, then again at col. 18, lines, 1-14, Lipshutz states as follows:

For example, reaction chamber 202 may be a sample collection chamber which is adapted for receiving a fluid sample such as a cell containing sample. For example, this chamber may include an opening to the outside of the device adapted for receipt of the sample. The opening will typically incorporate a sealable closure to prevent leakage of the sample, e.g., a valve, check-valve, or septum, through which the sample is introduced or injected. In some embodiments, the apparatus may include a hypodermic needle integrated into the body of the device and in fluid connection with the sample collection chamber, for direct transfer of the sample from the host, patient, sample vial or tube, or other origin of the sample to the sample collection chamber.

Lipshutz, col. 18, lines, 1-14. Here in both places, Lipshutz fails to disclose the claim limitation of the carrier being adapted to mate with the device *to form a reaction chamber* (emphasis added). In contrast, Lipshutz discloses a chamber which is already formed and then pierced with

a needle at a septum, or an already formed chamber with a valve to open. For these reasons, Lipshutz does not anticipate the present invention as claimed.

Also, Lipshutz does not appreciate one of the advantages of the present invention which is the ease of introducing sample into the chamber. In contrast, Lipshutz discloses using a needle, piercing a septum, or including a valve. Hence, in Lipshutz, the sample has to be obtained, placed into a form that can be introduced into a needle if not already in the needle or if the needle is integrated with the chamber, then sample has to be drawn into a needle and then removed from the needle and delivered into the chamber with a step of opening a valve or piercing a septum and then closing the valve. The needle is an intermediary device that raises the potential for contamination and increases the potential for sample remaining inside the needle. Furthermore, opening a valve and closing a valve as well as drawing sample into a needle are additional time consuming steps. As can be seen, Lipshutz does not appreciate advantages associated with the present invention.

Elsewhere in Lipshutz, Figures 2A and 2B disclose a chamber 104 and a first piece 102 and a second piece 124. However, the pieces 102 and 124 are not adapted to introduce sample to the reaction chamber upon mating. Instead, channels 122 and 110 are employed to introduce sample into the chamber. Hence, the claim limitation of the carrier being adapted to introduce the sample to the reaction chamber upon mating the carrier to the device is not anticipated. Therefore, the claim is believed to be allowable.

For these reasons, independent claims 1, 28, and 31 and their respective dependent claims are not anticipated by Lipshutz. Also, dependent claim 27 recites the limitation of the processing device being a laminated assembly and a centrifuge tube. This limitation is not disclosed by Lipshutz. With respect to dependent claim 29, Lipshutz does not disclose a second port being a stop junction. With respect to dependent claim 32, Lipshutz does not disclose a second chamber being a fluid reservoir. With respect to dependent claim 33, Lipshutz does not disclose a second chamber including a pump. With respect to dependent claim 34, Lipshutz does not disclose a third chamber fluidly coupled to the first chamber via the second conduit. With respect to

dependent claim 35, Lipshutz does not disclose a third conduit fluidly coupled to the third chamber. With respect to dependent claim 37, Lipshutz does not disclose a laminated assembly that includes a first layer; a second layer defining the second chamber, first conduit and second conduit; a third layer defining a fill port and stop junction holes; and a fourth layer defining the first chamber; wherein the second layer is located between the first layer and third layer; the third layer being located between the second layer and fourth layer. These claims are also not anticipated for the failure of Lipshutz to disclose at least these additional claim limitations.

*B. Claims 1 and 25*

Claims 1 and 25 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,221,655 to Fung et al. (hereinafter "Fung"). In particular, the Office states as follows:

The centrifuge tube is equivalent to Applicants' claimed sample processing device. The spin filter portion of the assembly is equivalent to Applicants' claimed sample carrier, since sample is carried on the filter frit and/or screen.

Paper No. 24, pg 3, paragraph 4. Applicants traverse this rejection because Fung is believed to be an improper reference under 35 U.S.C. § 102(e). Applicants' application for patent claims priority to U.S. Provisional Patent Application Ser. No. 60/093,744, filed on July 21, 1998 which predates Fung's filing date of August 1, 1998.

**Allowable Subject Matter**

Claim 30 has been objected to as being dependent upon a rejected base claim, but has been indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Accordingly, applicants have rewritten claim 30 in independent form incorporating all the limitations of the base claim. Therefore, applicants believe claim 30 is in a condition for allowance.

In view of the foregoing remarks, applicants respectfully submit that the application is in a condition for allowance, and action toward that end is earnestly solicited. The Office is invited

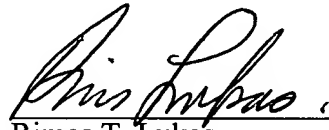
to contact the applicant's representative at the telephone number below if it is believed that a telephone conference would facilitate prosecution of this application.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time.

Respectfully submitted,

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By:



Rimas T. Lukas

Registration No. 46,451

Lukas IP Group  
P.O. Box 3295  
Half Moon Bay, California 94019-3295  
Telephone: (650) 560-0076  
Facsimile: (650) 897-9944